

REMARKS

The application is believed to be in condition for allowance.

Claims 36-61 are pending in the present application, claim 61 being newly added and based on claim 47. The recitations of claim 37 have been moved into claim 36. Claim 36 now includes the combined recitations of prior claims 41, 45, and 47.

The Official Action rejected claims 45 and 59 under Section 112, second paragraph, as being indefinite.

These claims have been amended so as to remedy the stated basis of rejection. These claims recite features of one preferred embodiment of the invention. In this embodiment, the simultaneous heating and cooling is indeed performed. This simultaneous heating and cooling further increases the mixture to achieve a homogenous temperature distribution within the reaction mixture contained in the reaction vessel.

Reference is made to at least specification page 3, third paragraph.

Withdrawal of the indefiniteness rejection is respectfully requested.

Claims 36, 42, 44, 46, 50, 56, 58 and 60 stand rejected as anticipated by CORBETT et al. (WO 98/49340).

Claims 37-41, 45-49, 51-55, and 59 stand rejected as obvious over CORBETT et al.

Claims 43 and 57 stand rejected as obvious over CORBETT et al. in view of HIEB et al. 5,323,667.

Claim 45 has not been substantively rejected. An indication of the allowability of claim 45 is solicited.

The recitation from claim 37 been added to claim 36 (within step B). The Official Action stated that CORBETT et al. was silent as to the amount of centrifugal force the vessel was exposed to. The Official Action further stated that absent a showing of criticality and/or unexpected results, it would have been obvious to determine the optimum amount of centrifugal force.

Indeed, the structure of CORBETT et al. does not provide the recited centrifugal force and cannot achieve the results of the present invention. CORBETT et al. clearly focuses on a disposable rotor having dimensions identical to those of an audio CD, where sample and reagents are driven through channels in the disks by centrifugal force. Thus, centrifugation is defined only as "spinning so as the reaction mixture and the sample DNA are moved by centrifugal force to the reaction well at the periphery of the rotor."

Cooling is achieved in CORBETT et al. by increasing the rotor speed, this resulting in that ambient air is drawn into the

chamber displacing the heated air previously in the chamber. Therefore, there is not simultaneous heating and cooling, and only when reaching completion, the reaction is stopped by pumping refrigerated air into the chamber.

The Official Action asserts that the CORBETT et al. device inherently provides the homogenous condition specified in claim 36. This is not the case and the Official Action has no basis for making this assertion. Applicants, through practical experience show that the device according to CORBETT et al. remains insufficient to create the surprisingly efficient and homogeneous mixture achieved in the method and structure of the present invention.

In the interest of advancing the case, the recitation from claim 37 is brought into independent claim 36. It is this centrifugal force that produces the results that are both novel and non-obvious over the CORBETT et al. device given the CORBETT et al. devices physical limitation and intended purpose.

In view of this, the presently pending claims 36 and 50 are both novel and non-obvious over the prior art. Accordingly, reconsideration and allowance of all the pending claims are respectfully requested.

The present application shows that a high centrifugal force is necessary to achieve the homogenization. This is a

surprising result that centrifugation and heating result in efficient mixing.

The dependent claims recite using air at a high temperature, 200-800°C, and in particular at 600°C. Although the Official Action has stated that such ranges would be obvious, there is no basis for saying that such ranges would be obvious for use with the CORBETT et al. device. Again consider the structure of the device and its intended purpose. One of skill in the art would not expect the CORBETT et al. device to be operated under these conditions. Indeed, one of skill in the art would appreciate that the teaching of the CORBETT et al. device would not be satisfactory as it is common knowledge that the reagents in the sample could overheat and become denaturated, or that the plastic vessels themselves would simply melt. In view of this, the obviousness rejection as to these recitations is believed to be non-obvious.

Again, although there may be known means for heating, the issue is whether such known means would be suitable with the CORBETT et al. device for the purposes disclosed. The use of such heating means in combination with very high centrifugal forces, is not believed to be obvious over the prior art (CORBETT et al.).

It is true that separate heating and cooling steps are employed in PCR processes. However, the prior art has not

appreciated, nor is it obvious, to simultaneously heat and cool.

One of skill in the art (as indicated by the Official Action itself) would think this counter-productive. It is only the present specification which teaches rapid mixing and homogenization taking place in the vessels where it is now an option to apply cooling to one end of the vessel while heating the opposite end. Indeed, such is believed to be clearly non-obvious.

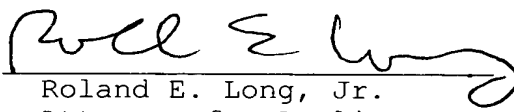
In summary, the claims are believed to be patentable because the recitations of both the independent claims and the dependent claims are believed to be both novel and non-obvious. As to the question of obviousness, it is important to consider the structure and disclosed nature/uses of the CORBETT et al. device. That there are other cooling, heating, spinning means available with different capabilities is not in and of itself a basis for modifying the CORBETT et al. device. As addressed above, the recitations of the presently pending claims are believed to be both novel and non-obvious. Therefore, applicants believe that the present application is in condition for allowance and an early indication of the same is respectfully requested.

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The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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